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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,128	03/04/2002	Wolf-Georg Forssmann	P67671US0	9771

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EXAMINER

HARLE, JENNIFER J

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 08/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/069,128	Applicant(s) FORSSMANN ET AL.	
	Examiner Jennifer I. Harle	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-14 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 15-21 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-14 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 8-14 were pending. Applicants' by Amendment attempted to cancel claims 1-4 and add claims 15-23. For the reasons previously set forth and as reiterated below, claims 15-21 and new claim 23 are not entered. Claim 22 will be entered.

Response to Amendment

Applicant's arguments filed July 1, 2004 have been fully considered but they are not persuasive.

Applicants' argue that the non-responsive Office Action of May 10, 2004 is mistaken for the following reasons:

- The examiner set forth the interpretation/meaning of the claims to be drawn to a method of making a medicament (See pg. 2 office Action, 31 December 2003) and that this is merely a statement by the PTO as to what the claims define, which is improper as it is Applicants' sole prerogative to define the claims as set forth in *In re Pilkington*, 162 USPQ 145, 148 (CCPA 1969).
- Claims 8-14 are not limited to a method of making a medicament, as the plain language of the claims show in generic claim 8 "for the treatment of a pathogenically altered bacterial flora in the gastrointestinal tract, respiratory and urogenital systems [and] the skin."
 - Claim 9 limits claim 8 to such use with a specific dosage amount and mode of administration.
 - Claim 10 limits claim 8 "for the treatment of laterations of the instestinal flora."

- Claim 11 limits claim 8 “for the treatment of alterations of microbially induced skin diseases.”
 - Claim 12 limits claim 8 to use “for the treatment of aberrations of the human vaginal flora.”
 - Thus, Applicants’ argue that claims 10-12 would have no meaning if, claim 8 were limited to a method of making a product.
- The examiner improperly creates a retroactive restriction requirement by belatedly alleging a lack of unity, which is unfounded.
 - The originally presented claims do not contain the subject matter found in the latter presented claims because the method-of-treatment subject matter is found in the originally filed claims and Applicants’ were denied the right to select the method of treatment subject matter.
 - Applicants’ further argue against the examiner’s interpretation that the only step that can be surmised in claim 8 is the combination of natriubiotics and a carrier suitable for either pharmaceuticals or food is wrong for two reasons:
 - It reads non-existing language into the claims, as the claims recite neither the combination step
 - It does not recite a carrier suitable for either pharmaceuticals or food.
- Applicants’ argue that the Office Action fails to consider either claims 20 or 21.

The examiner respectfully disagrees with Applicants' analysis. Applicants' submitted the preliminary amendment, dated 4 March 2002, canceling claims 1-7 and adding claims 8-14. These claims were clearly written in the form of "use" claims and were interpreted by the examiner utilizing Claim 8, which clearly states "Use of natriubitoic for the preparation of an antibioticly active agent for the treatment of ...". All other claims depended from claim 8. Applicants' citation of *In re Pilkington*, is not on point. Pilkington, merely stands for the proposition that Congress under 35 USC 112 placed no limitation on *how* an applicant claims *his invention*, so long as the specification concludes with claims which particularly point out and distinctly claim that invention. *In re Pilkington* at 148. This, as pointed out by the examiner is exactly what Applicants' failed to do. Applicants' failed to exercise any prerogative to specifically define the claims in a manner that would lead the examiner to a contrary interpretation. Thus, the examiner rejected claims 8-14 under 35 USC 101/112 and set forth an interpretation, following the procedures set forth in the MPEP 2173.05(q) "Use" Claims. Use of something for the preparation strongly represents that a method of making is being claimed.

Applicants' argue that the language, "for the treatment of a pathogenically altered bacterial flora in the gastrointestinal tract, respiratory and urogenital systems [and] the skin" demonstrates the plain language of the claim towards treatment and not a method of making. However, Applicants' totally ignore the first part of their own claim, which the examiner had already utilized to interpret the claim (see argument as set forth above) and attempt to alter the meaning of the claims from a method of making to a method of treating/using. Applicants' state that the claim language revolves around this part of the claim but do not argue the examiner's interpretation or show how his reasoning was flawed merely that they should have the right of

another examination. Thus, the argument is deemed not persuasive, and the interpretation of claim 8 as a method of making is maintained.

Applicants' further arguments that claims 9 and 10-12 would have no meaning in a process claim and therefore demonstrate the error of the examiner's interpretation are flawed. The examiner does not find this argument persuasive as claim 8 was drawn to a method of making. See the Non-Responsive Communication, mailed 25 May 2004.

Applicants' final argument is directed to an improper lack of unity because they were not allowed to select between a method of making and a method of treating. As previously set forth, a method of making has been examined and an action issued. Moreover, see the Non-Responsive Communication, mailed 25 May 2004.

Newly submitted claims 15-21 and 23 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicants' originally presented claims were directed to a method of making natriubiotics and Applicants' are arguing the method of treating/using natriubiotics.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 15-21 and 23 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 101/112

The previous 35 USC 101/112 rejections of claims 8-14 are incorporated in their entirety and made final.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-14 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Forssmann, et al. (CA 2,188,143) as the English language equivalent of WO 95/28952 and made final.

Forssman discloses making a preparation comprising the same natriuretic peptides as the instantly claimed pharmaceutical compositions (pg. 2, paragraphs 1-2, i.e. brain natriuretic peptide (BNP), phosphorylated urodilating, phosphorylated ANP, Example on page 3; usual diluents, vehicles, fillers or auxiliary agents for bronchial diseases administered parenterally, IM subQ, as an aerosol, IV or by inhalation, i.e. as a spray, within the claimed dosing ranges set forth in Applicants' specification, see claims 1-4). Moreover, typical pharmaceutically acceptable solution, in this case, apparently are nothing more than water of physiological sale, and are quite suitable as food additives.

As per claim 22, Forssman discloses combining an effective amount of a natriubiotic together with a pharmaceutically acceptable carrier (pg. 2, paragraphs 1-2, i.e. brain natriuretic peptide (BNP), phosphorylated urodilating, phosphorylated ANP, Example on page 3; usual diluents, vehicles, fillers or auxiliary agents for bronchial diseases administered parenterally, IM subQ, as an aerosol, IV or by inhalation, i.e. as a spray, within the claimed dosing ranges set forth in Applicants' specification, see claims 1-4). As the combination is identical, and one is

merely combining the two with no specific steps involved, it would inherently make an antibacterial agent. See MPEP 2112.01.

In the instant claims, the preamble has been considered to determine if the antibacterial activity, materially changes, the claimed steps. As previously set forth and reiterated once again, the claims recite a method preparation of natriubiotics. How one uses the composition does not materially change the actual physical steps of making the composition.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Vollmar, et al., Effects of atrial natriuretic peptide on phagocytosis and respiratory burst in murine macrophages, European Journal of Pharmacology, Vol. 319, 1997, pp. 279-285 discloses that data that ANP plays an important role in the immune system.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1654

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The previous Office Actions are incorporated in their entirety.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer Ione Harle
August 9, 2004

MICHAEL MELLER
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'M. Meller', with a long horizontal flourish extending to the right.